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Title:

Total arthroplasty of basal thumb joint with Elektra prothesis: an in vitro analysis

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Keywords:

Carpometacarpal joint, uncemented trapeziometacarpal prosthesis, principal cortex strains, finite element models, stress-shielding.

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Abstract

The reported outcomes of the Elektra thumb carpo-metacarpal joint implant have been very variable. This study evaluates the influence of daily cyclic loads and the type of the screw-fit cup insertion technique in the trapezium, with and without prior threading, on the structural bone behaviour. The study was performed experimentally to predict initial implant stability and cortical bone strains. Computational models were developed to assess the structural cancellous bone behaviour. The use of Elektra implant changed considerably the bone strain behaviour comparing to the intact joint. This may be associated with risks of cancellous bone fatigue failure due to overload, particularly in the trapezium. The joint load magnitude has a more important structural role than that of the screw-fit cup insertion technique. Limiting the magnitude of thumb loads after arthroplasty may contribute positively to the longevity of this procedure.

Level of evidence: V

Introduction

The primary goals of the painful arthritis of the thumb treatment are: to restore thumb function, to eliminate, or at least reduce the pain, to secure a stable, mobile joint and to maintain strength. Numerous surgical techniques have been described for the treatment of thumb carpo-metacarpal (CMC) joint osteoarthritis (OA) (Colegate-Stone et al., 2011; Hentz, 2013; Ladd et al., 2014). Trapeziectomy with ligament reconstruction has been considered the gold standard; however, proximal migration of the thumb metacarpal has been reported, resulting in reduction of pinch strength, while total arthrodesis is associated with decreased motion range (Lazetta et al., 1995; Roberts et al., 2001; Taylor et al., 2005; Hentz 2013; Ladd et al., 2014; Smeraglia et al., 2015; Singh et al., 2015). To overcome these problems, total joint arthroplasty was introduced by de la ca Caffiniere in 1971 (Hentz, 2013; de la Caffiniere and Aucouturier, 1979). Several articles on thumb carpometacarpal joint total arthroplasty have indicated very different outcomes (Matullo et al., 2007; Hentz, 2013; Vitale et al., 2013; Huang et al., 2015; ten Brinke et al., 2016; Thillemann et al., 2016; Tandara et al., 2016). These reports have shown that the main cause of failure/revision is loosening/dislocation of the trapezium cup and pain (Wachtl et al., 1998; Matullo et al., 2007; Hansen et al., 2008; Vitale et al., 2013; Hentz, 2013; Duerinch and Caekebeke 2016; Krukhang et al., 2014). In order to improve the outcomes of thumb arthroplasty several prostheses have been subjected to design changes over time. An example is the uncemented Elektra prosthesis (Small Bone Innovations, Peronnas, France), which has evolved since 1997 (Regnard, 2013). The reported results of the Elektra implant are very variable with some good outcomes (Regnard, 2006; Ulrich et al., 2008; Regnard, 2013; Hansen and Stilling, 2013; Chung et al., 2014) and some bad to very bad outcomes (Hansen and Snerum, 2008; Hernández-Cortés et al., 2011; Klahn et al., 2012). Research on the biomechanics of thumb CMC joint arthroplasty is very limited, but recent experimental and clinical studies suggest that threading of trapezium prior to insertion of uncemented screw-cup Elektra weakens the primary fixation strength of the implant (Hansen et al., 2011; Hansen et al., 2013).

The hypothesis considered in this study is that the magnitude of thumb CMC joint cyclic loads in daily hand function, combined with a screw-fit cup insertion technique (with or without prior threading), generates different bone strain/stress and initial implant stability behaviour relatively to the intact joint, which may alter longevity of the implant.

The aim of this study was to assess the magnitude of daily loads over the thumb CMC joint arthroplasty with a screw-fit cup and whether this varied with prior threading of the bone.

Materials and Methods

Synthetic bones

Five synthetic trapezium and thumb metacarpal bones were manufactured since they were not commercially available (Fig 1). We made a foam core to mimic cancellous-bone and a shell of glass fibre and epoxy resin to mimic cortical-bone (Fig 1). The bone cortical geometry was obtained from CT scans of the left hand of a 35 year old man, that were converted to 3D models with an image processing software package (ScanIP, Simpleware Ltd. Exeter, UK). The foam core was obtained by CNC machining of blocks of solid rigid polyurethane foam (mod. 1522-03, Pacific-Research-Labs, WA, USA). This foam provides a consistent and uniform material with mechanical properties in the range of human cancellous-bone; it is used as a standard material for testing orthopaedic devices and instruments [ASTM F-1839-08 (2012)]. Subsequently, the foam core was layered with short-glass-fiber-reinforced epoxy resin until a mean thickness of 1.5 mm was achieved, matching the mean cortical thickness observed in the CT scans.

Implantation

Elektra thumb CMC joint total prostheses (Elektra) (Small Bone Innovations, Peronnas, France) were implanted using the standard surgical protocol (TMC Elektra Implant – Surgical Technique) by an experienced surgeon (Level III – Specialist) (Tang, 2009) (Fig 1). The implants were fixed into the bone models in the same positions with the help of two reference axes marked on the outer cortical surfaces to maximise consistency; the positions of the components were also measured using a 3D coordinate measuring machine (Model Maxim, Aberlink, UK). On the trapezium two types of screw-fit cup insertion techniques were used; with or without prior threading.

Testing

Four triaxial strain gauges (KFG-2-120-D17-11 Kyowa-Electronic-Instruments, Japan) were glued with a cyanoacrylate adhesive onto the base of the thumb metacarpal and three on the trapezium before prosthesis insertion (Fig 1). The strain gauges were connected to a data acquisition system PXI-1050 (National-Instruments, USA) before implant insertion. Four experimental joint reaction forces were applied simulating pinch and grasp, resulting from a combination of two flexion-extension alignments (40º and 20º) with two load magnitudes (Fig 1). A lateral pinch task (1kg), which generates an average thumb CMC joint contact force of 111N (Cooney and Chao, 1977) and a grasp task (10Kg), which generates an average thumb CMC joint contact force of 1223N (Cooney and Chao, 1977), were applied by the loading equipment (controlled through a load cell) before and after implantation (Fig 1). These loads were applied to implants with the two different types of screw-fit cup insertion. In order to establish correlations with finite element models and evaluate the risk of failure of the supporting cortical, the maximum-ε1 (tensile) and minimum-ε2 (compression) principal strains - within the plane of the strain gauge - were calculated. The standard deviations were determined over the five tests for each load-case and screw-fit cup insertion technique. The screw-fit cup and stem initial stability were evaluated after 25,000 load cycles at a frequency of 1Hz, for each load-case through a pull-out movement.

Finite element analysis

Finite element (FE) models of the intact and implanted structures of the trapezium and thumb metacarpal were built from CT-scans of the experimental models that were converted to 3D models with an image processing software package (ScanIP, Simpleware Ltd. Exeter, UK). This was to assess the mechanical cancellous bone behaviour in a stable, well-fixed implant. The implant models were created with a CAD modelling package (Catia, Dassault-Systèms, France). The finite-element models were composed of a total of approximately 60,000 four-node, tetrahedral elements. Non-linear contact formulation analysis was performed with ABAQUS (6.12-1) (Providence, USA). The trapezium-cup and thumb metacarpal-stem interfaces were modelled using a surface-to-surface contact algorithm with a coefficient of friction of 0.3 (Shirazi-Adl et al., 1993; Viceconti et al., 2000; Completo et al., 2010). The materials were assumed to be homogeneous, isotropic and linearly elastic. The elastic modulus values used for the screw-fit cup, stem, cortical and cancellous-bone were 210 GPa, 110 GPa, 16.7 GPa and 0.155 GPa, respectively. The Poisson's ratio was considered to be 0.3 for all materials. The applied loads in the FE models replicated those used in the experimental setup. The two types of screw-fit cup insertion techniques were modelled through a contact interference-fit formulation. The screw-fit cup insertion with prior trapezium threading was modelled with a 0.02mm press-fit, while the insertion without prior threading was modelled with a press-fit of 0.3mm (~thread height) at the thread crest regions. For comparison purposes, a rigidly bonded bone-implant interface with full bone-implant adhesion, representative of a stable long-term bone implant interface, was also modelled. Cortical bone strains acting on the gauge planes were selected as corresponding to the experimental strain measurement sites.

Statistical analysis

In the biomechanical models an exploratory data analysis with a Shapiro-Wilk test was made in order to check the normal distribution of all data. Paired t-tests were performed (SPSS, USA) to evaluate the statistical significance of the difference of the mean principal cortical strains. Regression analysis was performed for the measured cortical strains and for those predicted by the FE models. The root-mean-square-error was calculated and expressed as a percentage (RMSE %) of the peak values of the measured principal cortical strains. In addition, to evaluate the risk of failure of cancellous bone in compression a comparative analysis of the minimum principal strains was conducted.

Results

The mean and standard deviation of the principal cortical strains for each strain gauge are depicted in Fig 2, for grasp (1223 N, 40º) and lateral pinch (111N, 20º) loads. The two other flexion-extension alignments analysed for both loads did not substantially alter the cortical strain behaviour. The standard deviation of the mean principal strain was less than 12% for the trapezium or thumb metacarpal. The grasp load at the trapezium produced, on average, ten times higher cortical strains than the lateral pinch load, except in the implants without prior threading, which showed the highest principal strains for both loading scenarios. Significant minimum principal strain differences were shown between the intact models and the prostheses implanted with prior threading (Table 1) in the Dorsal (T_D) and Lateral (T_L) strain gauges ($p<0.05$). Significant maximum principal strain differences ($p<0.05$) were registered at the Medial (T_M) and Dorsal (T_D) strain gauges between intact models and for the prostheses implanted without prior threading. For the thumb metacarpal the highest principal strains were measured in the intact models for both loading scenarios (Fig 2). Significant principal strain differences were seen in all metacarpal strain gauges between intact models and the prostheses ($p<0.05$), most marked for grasping (Table 1).

After 25,000 load cycles (1Hz) the screw-fit cups (with and without prior threading) and the metacarpal stems were stable on pull-out testing. In the trapezia and the thumb metacarpals, the correlation values (R^2) between FE and experimental principal cortical strains were 0.93 and 0.90 respectively, while the slopes of the linear regression models were 1.19 and 1.05 respectively. The overall absolute difference between numerical and experimental cortical strains (RMSE %) was 14% for the trapezia and 11% for the thumb metacarpals. Both types of the screw-fit cup insertion techniques increased the cancellous bone strains around the screw-fit cup several times (3 to 20 times) compared to the intact model. This was more marked, for the trapezium bones with cups inserted without prior threading (Fig 3). In the thumb metacarpal the cancellous bone strains around the stem increased compared to the intact model, for all loading scenarios (Fig 4). The FE modelling of long-term stable bone-implant interfaces showed a mean strain reduction of 2 and 4 times for the trapezium and thumb metacarpal bones respectively, (Fig 5) comparing to the recently implanted models.

Discussion

The standard deviation of the measured cortical strains was in range of those published elsewhere for other synthetic bones (Completo et al., 2008; Meireles et al., 201). The average cortical strains in the implanted trapezia presented a tendency to either remain constant or even reduce, when the screw-fit cup was inserted with prior bone threading. The strain reduction at the lateral region, greater than 1,000 µstrain for the grasp load, may present a risk of trapezium cortical resorption since it is known that, in situations where bone loads are reduced or eliminated, bone mass is reabsorbed (Gross and Rubin, 1995). In contrast, when the screw-fit cup was inserted without prior trapezium threading, a general cortical strain increase was observed. For some strain gauges, mainly for the grasp load, the higher cortical maximum principal strain (tensile) values (>2,000 µstrain) may be considered pathological (Frost H., 2003). The cortical strains in the implanted thumb metacarpal presented a significant reduction comparing to the intact situation, particularly for the grasp load. No sign of instability was observed on the screw-fit cup, for either insertion technique.

The failure of the supporting cancellous bone can be due to overload (compression) and is usually a fatigue mode characterized clinically by repetitive loading, gradual pain, and bone resorption (Taylor and Tanner, 1997) or failure described by Wolff's law; i.e. in situations where bone loads are reduced or eliminated, bone mass is reabsorbed. The developed FE models for the evaluation of the cancellous bone strain produced results which compare well with the experimental data in terms of correlation values, slope of the linear regressions and RMSE values which are within the range of previously published data (Completo et al., 2010; Completo et al., 2011). Therefore, the validity of the FE models is reasonably well proven. For both bone models the introduction of the

Elektra implant tended to increase the cancellous bone strains comparing to normal. However, when the screw-fit cup was inserted without prior trapezium threading, the high strain regions were more extensive than those with prior threading. The strain increase indicates a potential risk of cancellous bone fatigue failure for both the implanted trapezia and thumb metacarpals; bone can suffer fatigue failure if the induced strain approaches 60-80% of the yield strain (Choi et al., 1992). This can represent a serious damage risk at over one million cycles. However, this failure risk is only present if the thumb load is in the range of this study (daily activities) and the load is applied immediately after arthroplasty (here simulated through a contact with friction bone-implant interface). Thus, it would appear to be prudent for some time (how long is unknown) following a thumb arthroplasty to avoid normal daily hand functions, considering that even a lateral pinch (1kg) action generates a cancellous bone strain increase greater than 100% for both bone structures. Once full bone-implant anchorage has occurred (here simulated through a rigidly bonded bone-implant interface in the FE model), the cancellous bone strains were about half those obtained in the immediate postoperative scenario for both structures. However, in the trapezium - for the grasp load - they are still approximately ten times higher than the intact strain values. Thus this still presents a risk of cancellous bone suffering fatigue failure. In this context, daily activities with load magnitudes substantially lower than grasp (10kg), lateral pinch (1kg) or tip pinch (1kg) load will reduce/minimise the risk of bone fatigue failure both for trapezium and thumb metacarpal. However, how this can be feasible it is unclear.

Comparative studies on the state of stress/strain in CMC joint between intact thumbs and following an Elektra total arthroplasty are very limited. There are some clinical and in-vitro studies (Hansen et al., 2011) with the Elektra implant. The clinical outcome of

Elektra implant reported is controversial, with a great variability in rates of revision Some studies report low rates (Regnard, 2006; Ulrich-Vinther et al., 2008; Regnard, 2013; Hansen and Stilling, 2013; Chung et al., 2014), whilst others find the results unacceptable (Hansen and Snerum, 2008; Hernández-Cortés et al., 2011; Klahn et al., 2012). These clinical results do not contradict the present study, as the main failure occurs in the screw-fit cup in the trapezium due to loosening. This finding is in line with the marked increase in cancellous bone strain identified in this study around the screw-fit cup comparing to the intact joint for daily loads on thumb, mainly in the early postoperative condition. It is reasonable to expect cancellous bone to suffer fatigue failure if the induced strain of the intact joints is increased by 50-100% due to implantation (Burstein and Wright, 1994), as in this study. For the longevity of this procedure, it appears that magnitude of the joint loads is more important than the screw-fit cup insertion technique.

As in all experimental-numerical studies, the present study also has shortcomings. One limitation is the use of synthetic bones and the simplifications made in the experiments to represent the functioning joint. Another issue is the use of a CT scan from a male of 35 years and not of a woman in the 50's with thumb CMC joint osteo-arthritis. However, the use of artificial bones increases reproducibility reducing the number of tests. Another limitation concerns the experimental load-cases which were simplified in terms of structural links - ligaments and muscles, among others, between trapezium and thumb metacarpal. Nonetheless the applied load-cases are representative of the major loads acting upon the implant and bone structure for thumb loads in the range of daily activities.

In conclusion the main insight from this study is that the use of Elektra implant changes the biomechanical behaviour of the trapezium and thumb metacarpal enough to risk bone fatigue failure by overload, particularly at the trapezium, for thumb loads in the range of daily activities. The magnitude of the joint load appears to be more important for the longevity of the implants than the screw-fit cup insertion technique in the trapezium. Nevertheless, insertion without prior threading appears preferable to improve early press-fit fixation of the screw cup, and may possibly prevent the previously reported high and early clinical failure rates. Limiting the loads over the thumb during the initial period (perhaps 6 weeks, followed by a progressive load increase) after a thumb CMC joint arthroplasty may improve implant longevity.

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TABLES

Table 1 – p values from the t tests, performed to test the difference of the mean cortical strains between the intact and implanted trapezium and thumb metacarpal models for grasp and lateral pinch loads (ε – principal strain).

Hand activity	Grasp at 40° Flex.-Ext				Lat. Pinch at 20° Flex.-Ext			
Trapezium	Intact *versus*				Intact *versus*			
	prior threading		without prior threading		prior threading		without prior threading	
Principal Strain	**ε2 (minimal)**	**ε1 (maximal)**	**ε2 (minimal)**	**ε1 (maximal)**	**ε2 (minimal)**	**ε1 (maximal)**	**ε2 (minimal)**	**ε1 (maximal)**
Medial - strain gauge **T_M**	0.119	0.105	0.016 *	p<0.001 *	0.736	0.026	0.001 *	p<0.001 *
Dorsal - strain gauge **T_D**	p<0.001 *	0.136	0.155	p<0.001 *	0.003 *	0.415	0.001 *	p<0.001 *
Lateral - strain gauge **T_L**	p<0.001 *	p<0.001 *	0.002 *	0.271	0.004 *	0.078	0.053	p<0.001 *

Thumb metacarpal	**Intact *versus* implanted**		**Intact *versus* implanted**	
Principal Strain	**ε2 (minimal)**	**ε1 (maximal)**	**ε2 (minimal)**	**ε1 (maximal)**
Medial - strain gauge **M_M**	p<0.001 *	0.051	0.120	p<0.001 *
Dorsal - strain gauge **M_D**	p<0.001 *	p<0.001 *	0.004 *	0.259
Lateral - strain gauge **M_L**	p<0.001 *	0.002 *	0.100	0.118
Palmar - strain gauge **M_P**	p<0.001 *	p<0.001 *	0.004 *	p<0.001 *

LIST OF FIGURES LEGENDS

Figure 1 – a) Elektra prosthesis stem and cup; b) Loading device and experimental setup; c) Joint extension alignment; d) Joint flexion alignment; e) Strain gauge positions in Lateral (M_L and T_L), Dorsal (M_D and T_D), Medial (M_M and T_M) and Palmar (M_P) sites at the thumb metacarpal and trapezium.

Figure 2 - Mean and standard deviation of the measured principal strains ($\varepsilon 1$ - maximum and $\varepsilon 2$ - minimum) for the trapezium and thumb metacarpal at each strain gauge location for the Grasp and Lateral Pinch activities.

Figure 3 - Minimum principal (compression) strains in cancellous bone of the intact and implanted trapezium for the Grasp and Lateral Pinch loads.

Figure 4 - Minimum principal (compression) strains in cancellous bone of the intact and implanted thumb metacarpal for the Grasp and Lateral Pinch loads.

Figure 5 - Minimum principal (compression) strains in cancellous bone of the implanted trapezium and thumb metacarpal for the Grasp load in a condition of full bone-implant adhesion.

FIGURES:

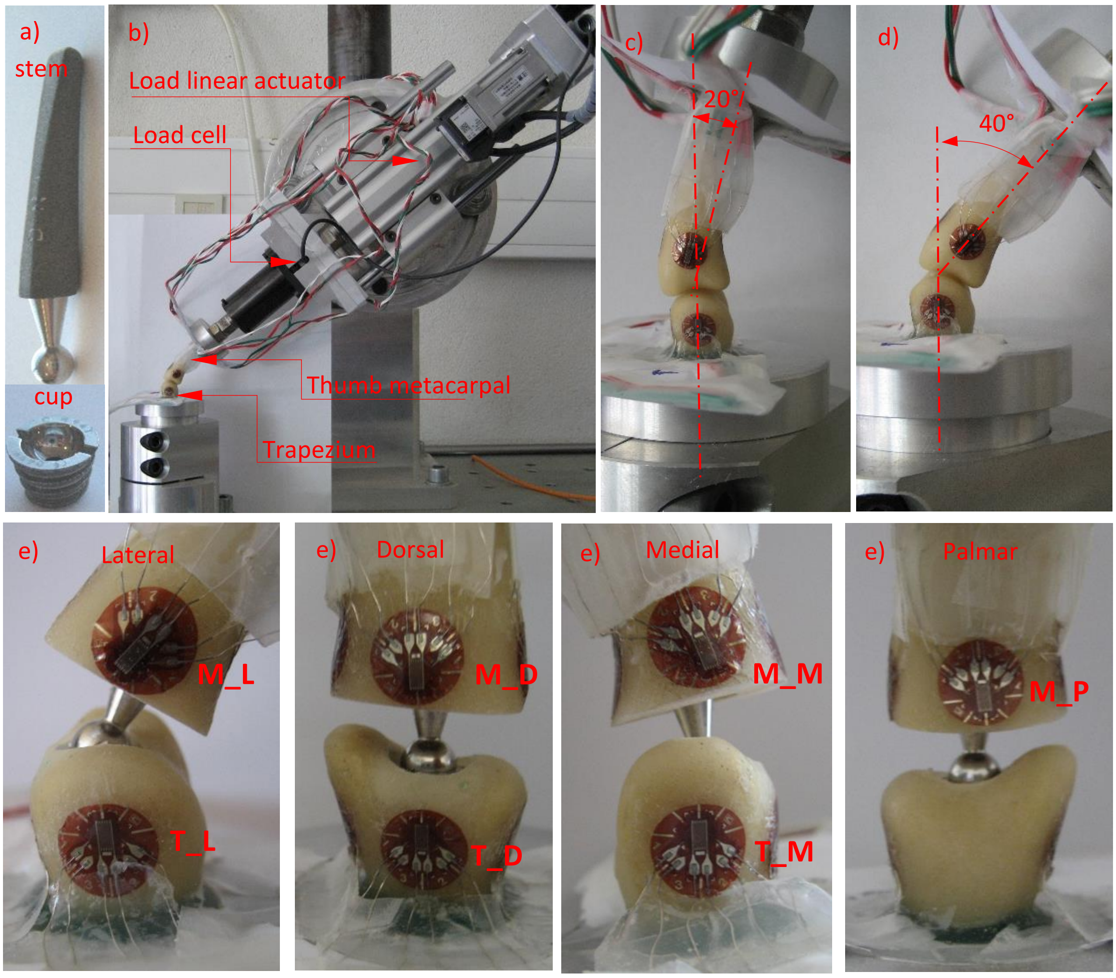
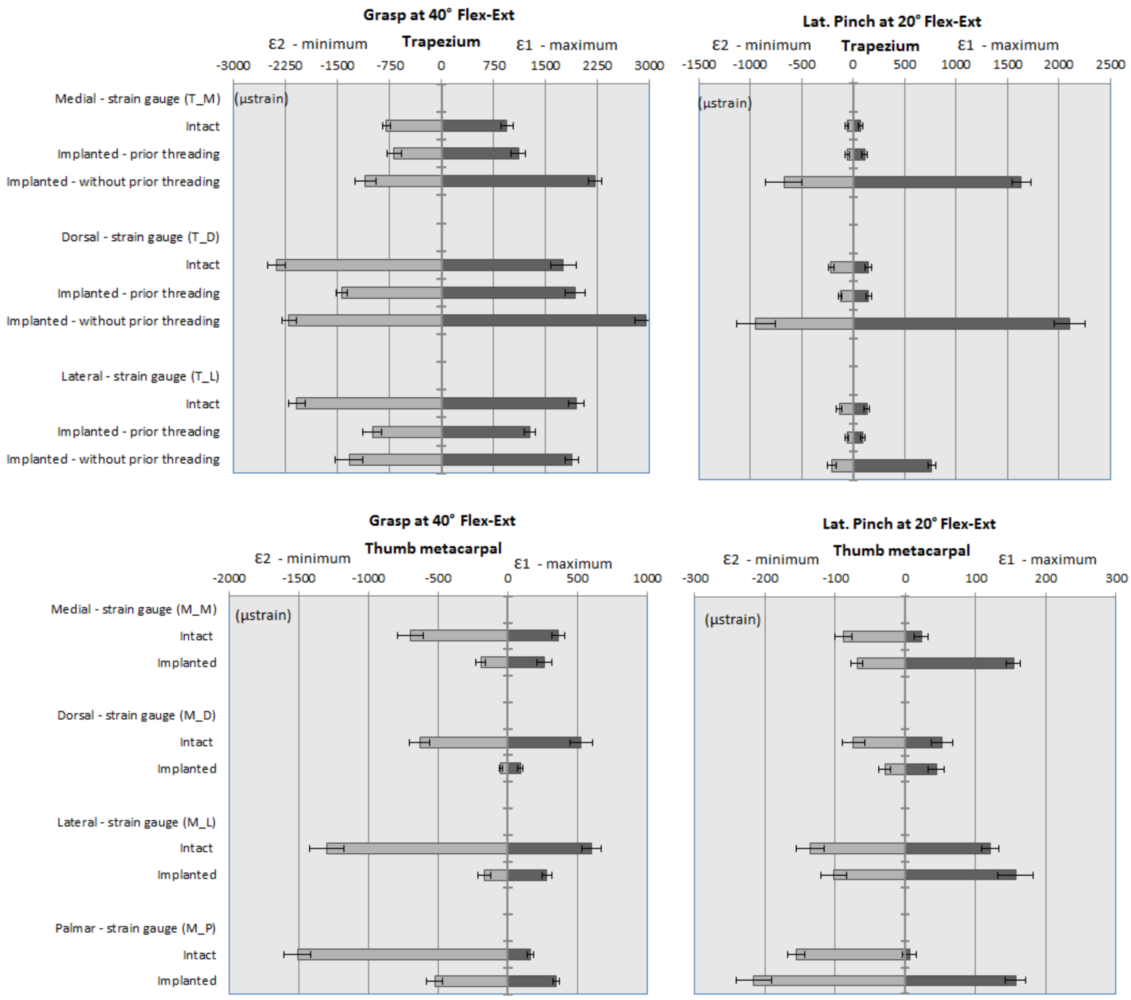


Figure 1



Grasp at 40° Flex-Ext
ε2 - minimum
Trapezium
ε1 - maximum
-3000 -2250 -1500 -750 0 750 1500 2250 3000
(μstrain)
Medial - strain gauge (T_M)
Intact
Implanted - prior threading
Implanted - without prior threading
Dorsal - strain gauge (T_D)
Intact
Implanted - prior threading
Implanted - without prior threading
Lateral - strain gauge (T_L)
Intact
Implanted - prior threading
Implanted - without prior threading
Lat. Pinch at 20° Flex-Ext
ε2 - minimum
Trapezium
ε1 - maximum
-1500 -1000 -500 0 500 1000 1500 2000 2500
(μstrain)
Grasp at 40° Flex-Ext
ε2 - minimum
Thumb metacarpal
ε1 - maximum
-2000 -1500 -1000 -500 0 500 1000
(μstrain)
Medial - strain gauge (M_M)
Intact
Implanted
Dorsal - strain gauge (M_D)
Intact
Implanted
Lateral - strain gauge (M_L)
Intact
Implanted
Palmar - strain gauge (M_P)
Intact
Implanted
Lat. Pinch at 20° Flex-Ext
ε2 - minimum
Thumb metacarpal
ε1 - maximum
-300 -200 -100 0 100 200 300
(μstrain)

Figure 2

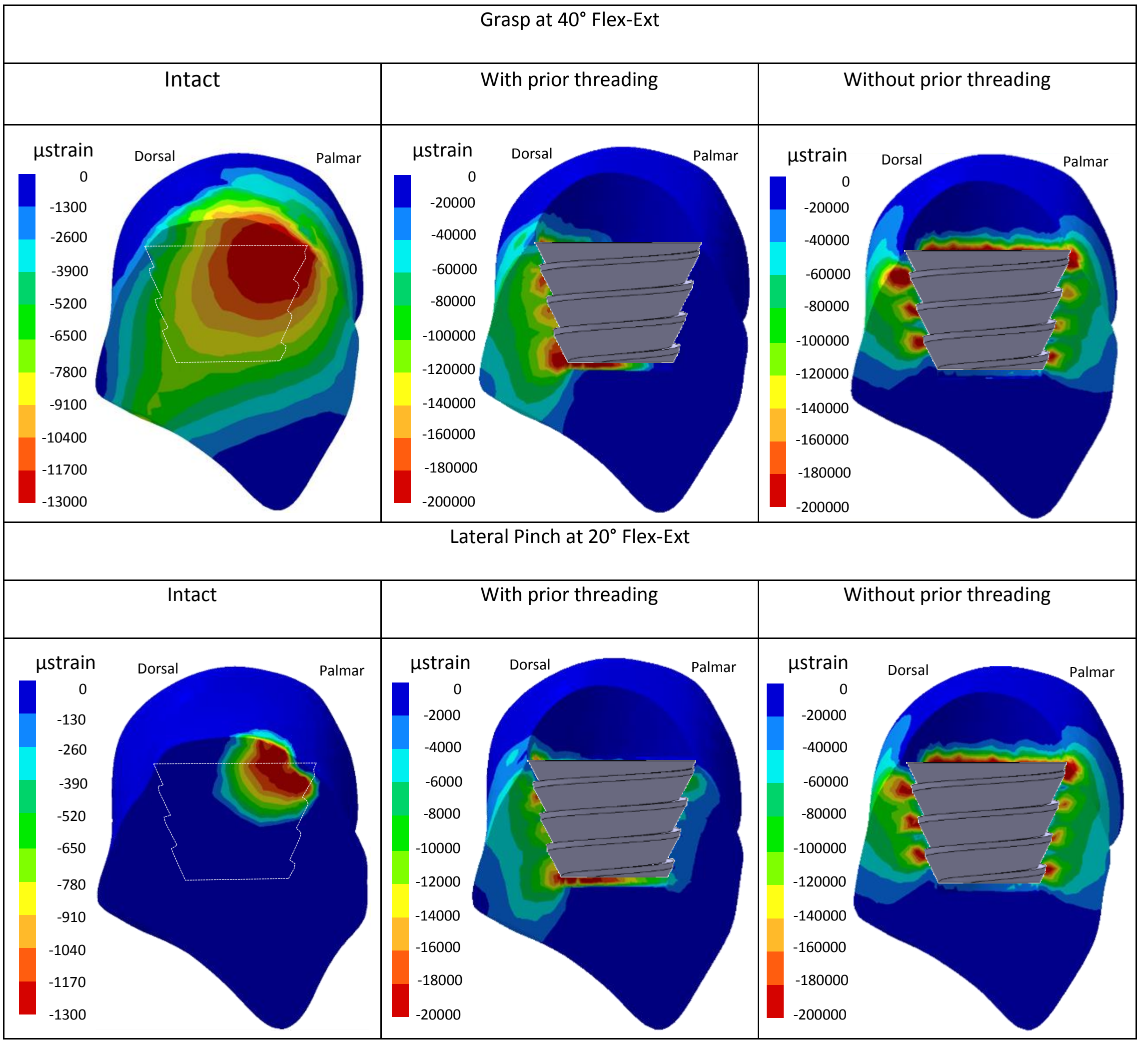

Grasp at 40° Flex-Ext
Intact
With prior threading
Without prior threading
µstrain
Dorsal
Palmar
0
-1300
-2600
-3900
-5200
-6500
-7800
-9100
-10400
-11700
-13000
0
-20000
-40000
-60000
-80000
-100000
-120000
-140000
-160000
-180000
-200000
Lateral Pinch at 20° Flex-Ext
0
-130
-260
-390
-520
-650
-780
-910
-1040
-1170
-1300
0
-2000
-4000
-6000
-8000
-10000
-12000
-14000
-16000
-18000
-20000

Figure 3

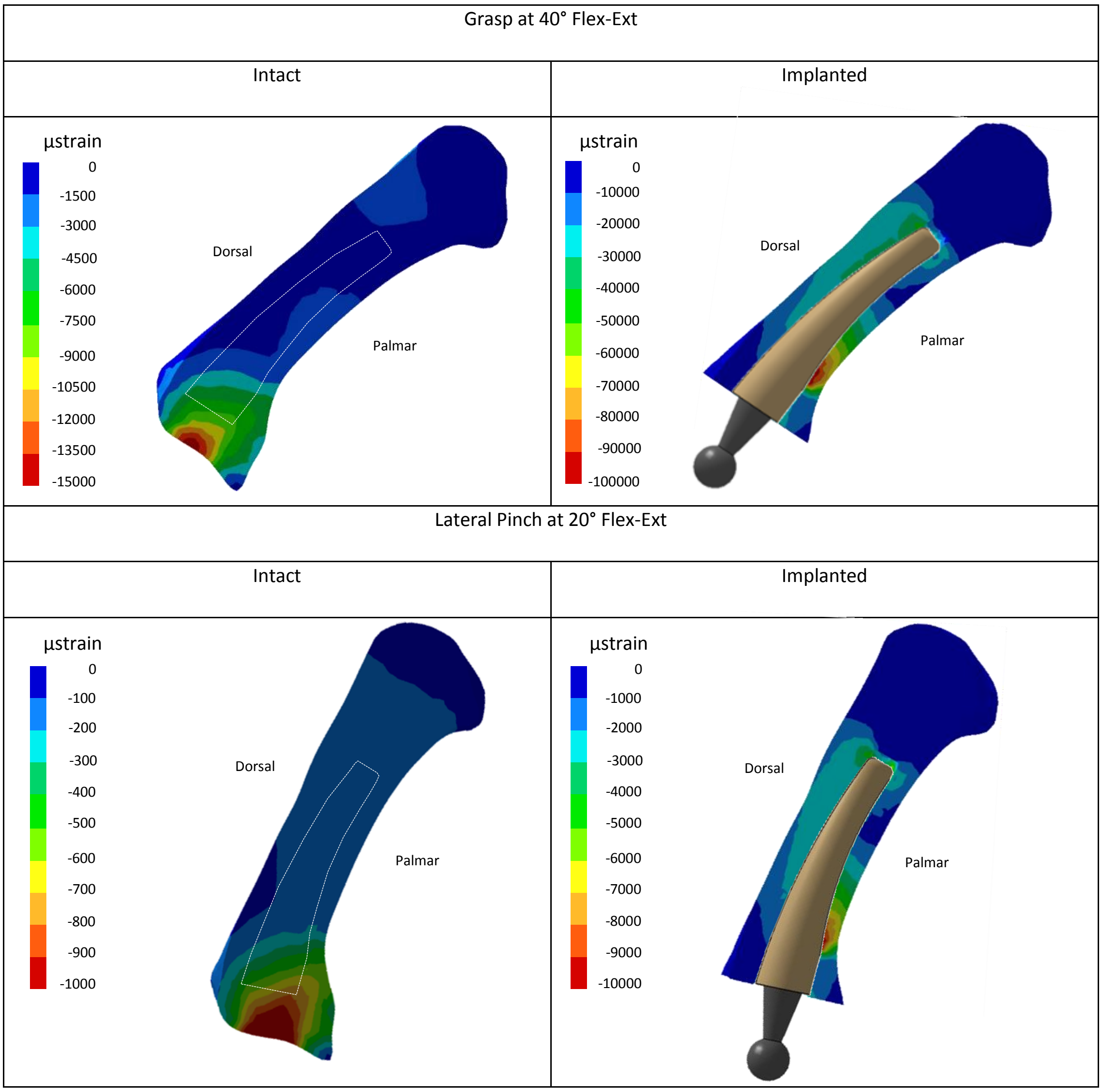


Figure 4

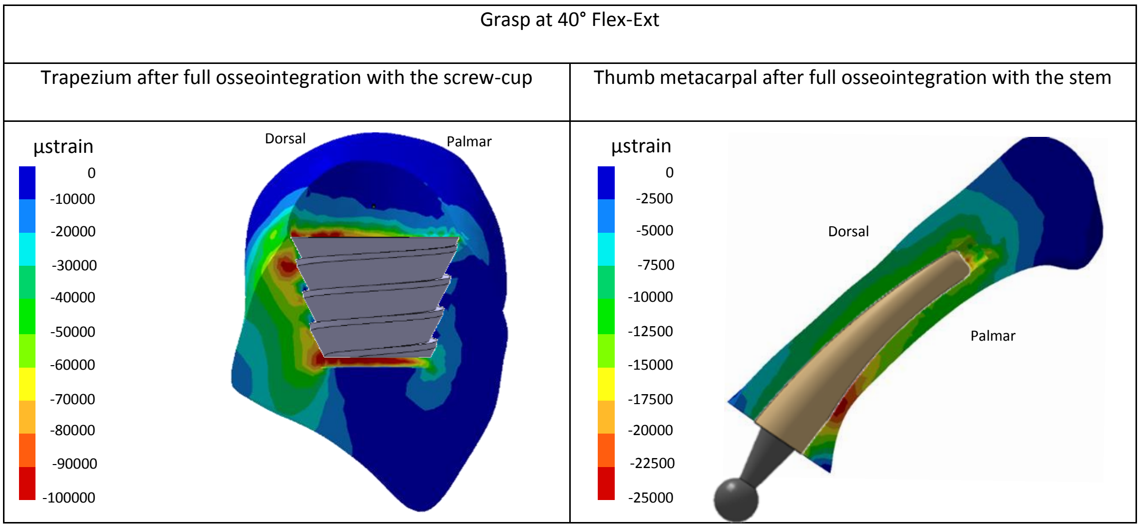


Figure 5